

QA: QA

U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE
AUDIT REPORT EM-ARC-01-13
OF THE
NATIONAL SPENT NUCLEAR FUEL PROGRAM
AT
IDAHO FALLS, IDAHO
SEPTEMBER 17-21, 2001

Prepared by: _____ **Date:** _____
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Navarro Quality Services

Approved by: _____ **Date:** _____
Robert D. Davis
Acting Director
Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit EM-ARC-01-13, the audit team determined that, with the exception of the identified conditions adverse to quality (CAQ), the National Spent Nuclear Fuel (NSNF) Program at Idaho Falls, Idaho, is satisfactorily and effectively implementing the examined portions of the Office of Civilian Radioactive Waste Management (OCRWM) QA Program in accordance with the U.S. Department of Energy (DOE) DOE/RW-0333P, Revision 10, *Quality Assurance Requirements and Description* (QARD) and applicable implementing procedures.

QA Program Sections 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 11.0, 16.0, 17.0, 18.0, Supplement I and Supplement III were determined to be effectively implemented based on the activities evaluated during the audit. Sections 8.0, 9.0, 10.0, 12.0, 13.0, 14.0, 15.0, Supplements II and IV, and Appendix A, B, and C are not being implemented at this time. Supplement V was determined not to be applicable at this time.

The audit team identified four CAQ during the audit, which resulted in the issuance of (1) two Deficiency Reports (DR): EM-01-D-144, assessment schedules failed to document completion of audits, track open DRs, or assign unique numbers as required by Project Management Procedure (PMP) 18.01, *Planning and Scheduling Assessments*; (2) EM-01-D-145, lack of timely corrective action to DRs and CAQ not identified as significant as required by PMP 16.02, *Corrective Action*, and QARD Section 16.0, "Corrective Action"; (3) one Deficiency Identification Referral (DIR) DIR-01-9 Memorandum of Agreement (MOA), DOE/SNF-MOA-001, Revision 0, between DOE/OCRWM and DOE/Office of Environmental Management (EM) not updated to reflect current organizations and no evidence of annual review as required by the MOA; and (4) one CAQ regarding completion of software installation testing documentation required only remedial action and was corrected during the audit (CDA).

The audit team evaluated the effectiveness of the corrective actions for six previously issued NSNF Program DRs as a result of last year's audit, EM-ARC-00-17. The audit team determined the corrective actions to be effective for four of those DRs, which have been closed, two remain open. The evaluation results are described in Section 5.5.4 of this report.

In addition, two recommendations resulting from the audit are documented in Section 6.0 of this report for NSNF Program management consideration.

The audit team identified noteworthy practices in the areas of training documentation and cross-checking, management tools used for deficiency tracking, records retrievability, and development/integration of the new implementing procedures.

2.0 SCOPE

Auditors representing the DOE Office of Quality Assurance (OQA) conducted a compliance-based audit to evaluate NSNF implementation of the OCRWM QA Program, as described in the QARD and implementing procedures. The audit team, through

interviews of cognizant personnel, reviews of documentation, and evaluation of procedures, assessed the adequacy and effectiveness of the NSNF implementation of the QA program. The audit was conducted at the NSNF offices in Idaho Falls, Idaho.

The audit team reviewed the status of the four closed OCRWM deficiency documents identified during the previous OCRWM OQA audit to determine the effectiveness of completed corrective actions by NSNF.

In accordance with the approved audit plan, the following QA Program Sections were evaluated:

QARD Program Sections

1.0	Organization
2.0	QA Program
3.0	Design Control
4.0	Procurement Document Control
5.0	Implementing Documents
6.0	Document Control
7.0	Control of Purchased Items and Services
11.0	Test Control
16.0	Corrective Action
17.0	QA Records
18.0	Audits
Supp I	Software
Supp III	Scientific Investigation
Supp V	Control of the Electronic Management of Data

The following QARD Program Sections were not reviewed during the audit since NSNF is not currently implementing them:

8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
12.0	Control of Measuring and Test Equipment
13.0	Handling, Storage, and Shipping
14.0	Inspection, Test and Operating Status
15.0	Nonconformances
Supp II	Sample Control
Supp IV	Field Surveying
Appendix A	High-Level Waste Form Production
Appendix B	Storage and Transportation
Appendix C	Monitored Geologic Repository

3.0 AUDIT TEAM

The following is a list of audit team members and their assigned areas of responsibility:

<u>Name/Title/Organization</u>	<u>QA Program Sections</u>
Patrick V. Auer, Audit Team Leader, Navarro Quality Services (NQS)	5.0, 6.0, and 17.0
James E. Flaherty, Auditor, NQS	1.0, 3.0, 11.0, 16.0, and Supplement III
Marilyn A. Kavchak, Auditor, NQS	18.0, Supplements I and V
James V. Voigt, Auditor, NQS	2.0, 4.0, and 7.0

4.0 AUDIT TEAM MEETINGS AND PERSONNEL CONTACTED

A pre-audit meeting was conducted at NSNF offices on Monday, September 17, 2001. Daily debriefings were held to apprise NSNF management and staff of the progress of the audit and any identified CAQ. A post-audit meeting was conducted at NSNF offices on Friday, September 21, 2001. Personnel contacted during the audit, including those who attended the pre-audit and post-audit meetings, are listed in Attachment 1, "Personnel Contacted During the Audit."

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, with the exception of those areas where CAQ were identified, the NSNF is satisfactorily and effectively implementing the examined portions of the QARD and applicable implementing procedures. The results for each QARD program section evaluated are contained in Attachment 2, "Summary Table of Audit Results."

5.2 Stop Work or Immediate Corrective Action Taken

There were no Stop Work Orders or immediate corrective actions taken as a result of the audit.

5.3 Audit Activities

Attachment 2, "Summary Table of Audit Results," provide results for each QA Program Section audited. The details of the audit, including the objective evidence reviewed, are documented in the audit checklist. The checklist is maintained as a QA record.

5.4 Technical Audit Activities

There were no technical areas evaluated during this audit.

5.5 Summary of Conditions Adverse to Quality

The audit identified CAQ, which resulted in the issuance of DRs EM-01-D-144, EM-01-D-145, DIR-01-9, and one CDA.

A synopsis of the CAQ documented on the DRs and DIR are detailed below. The DRs have been transmitted to NSNF under separate letters.

5.5.1 Corrective Action Request (CAR)

There were no CARs issued as a result of this audit.

5.5.2 Deficiency Reports

DR EM-01-D-144. NSNF PMP 18.01, requires each assessment schedule to identify specific items including; a unique identification number for each scheduled assessment and, the status of previously completed evaluation activities, including the status of open/closed findings. Fiscal year 2001 quarterly NSNF Program Assessment Schedules did not identify surveillances with unique numbers nor were the surveillances tracked through closure prior to being dropped from the assessment schedule.

DR EM-01-D-145. NSNF PMP 16.02, requires CAQ be evaluated against specified criteria such as “QA program breakdown” to determine whether the condition identified is significant. Three DRs were identified by NSNF, which indicates QA program breakdown. Additionally, QARD Section 16.1 requires CAQ be identified and corrected as soon as practical. Corrective actions are not being completed and closed in a timely manner; additionally, NSNF has had a DR open on the same subject for over a year.

DIR-01-9. DOE/SNF/MOA-001, Revision 0, signed July 24, 1997 between the Office of Nuclear Material and Facility Stabilization, EM, and OCRWM has not been updated to reflect current DOE organizations. Additionally, the MOA requires an annual review of the MOA to ensure conditions specified are still appropriate; however, there is no documented evidence that the MOA has been reviewed annually as required since July 1998 (this CAQ has been referred to DR EM-01-D-089).

5.5.3 Deficiencies Corrected During Audit

One software code, GOTH-SNF, has been installed and used without completing the approval cycle for the installation test documentation in

accordance with PMP 19.01, *Software Control*. The software code was not being used to generate quality-affecting data, only for preliminary testing. The data was deleted from the only computer on which it was stored during the audit as there was no impact to the scientific/engineering investigation.

5.5.4 Follow-up of Previously Issued Deficiency Documents

EM-00-D-138. There is no documented objective evidence in the NSNF Records Processing Center (RPC), filed under PMP 4.01, *Acquisition of Products and Services*, that NSNF performed annual supplier performance evaluations. Additionally, PMP 4.01, Subsection 4.3e, addresses supplier performance evaluations, but fails to provide the methodology.

PMP 4.01 was revised to incorporate methodology to perform supplier performance evaluations. Evaluations have been submitted to RPC. The corrective action was determined to be effective.

EM-00-D-139. The MOAs for DOE Sites at Savannah River, Hanford, Oak Ridge, and Idaho National Engineering & Environmental Laboratory failed to require implementation of the QARD's latest revision. The QARD Requirements Matrices do not reflect QARD, Revision 10, and two MOAs failed to require the contractor to review QARD revisions to determine impacts on site QA program and prepare a schedule for program and procedure revisions.

This DR remains open and corrective action is scheduled to be completed on September 30, 2001.

EM-00-D-140. Document Action Request (DAR) NSNF-125 failed to list all the affected PMPs; DAR NSNF-260 listed several PMPs. At least one PMP, 6.02, *Preparation of Technical Documents*, had no DAR or pending change; DAR NSNF-194 identified the change affects the QARD Matrix in total; however, no changes to the QARD Matrix were made.

DARs were issued to initiate the revision process in all cases reviewed and the appropriate QARD matrix was revised. The corrective action was determined to be effective.

EM-00-D-141. The Document Review Transmittals (DRT) and Review and Comment Records (RCR) were not completed for three MOAs prior to submittal and distribution of the MOAs. The DRTs and RCRs were not in the RPC within the 60-day requirement.

The DRTs and RCRs were completed for all documents reviewed. Additionally, a sampling of records in the RPC did not show any as having been submitted past the 60-day limit. The corrective action was determined to be effective.

EM-00-D-142. PMP-16.03, Revision 0, *Quality Assurance Trending*, only allows a cause code for each deficiency document and does not address the assignment of codes for multiple deficiencies on one document. Deficiency documents had multiple elements with different corrective actions, and the PMP does not address how a single cause code is assigned. Assigned cause codes were not consistent with accepted corrective actions. Root cause determinations may have multiple cause codes identified, but the initial assigned cause code was not changed to reflect the root cause determination.

PMP 16.03 was revised to incorporate assignment of codes for multiple deficiencies and further define the trending process. The corrective action was determined to be effective.

EM-00-D-143. NSNF has neither scheduled nor conducted performance-based audits of internal or external work.

This DR remains open and corrective action is scheduled to be complete on October 15, 2001.

6.0 RECOMMENDATIONS

Two recommendations resulting from the audit are presented below for the NSNF management's consideration:

1. Include electronic data controls in procedures due to increasing work in the areas of scientific investigation and software.
2. The NSNF Program should clarify the methodology within the records system to trace deliverable reports to the work package, supporting technical report, and data that generated the report.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Summary Table of Audit Results

ATTACHMENT 1
PERSONNEL CONTACTED DURING THE AUDIT

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Arenaz, M. R.	DOE/ID/NSNF/Manager			X
Armour, D. A.	NSNF/QA Specialist	X	X	X
Blyth, R. L.	NSNF/QA Specialist	X	X	X
Dahl, C. A.	NSNF/Advisory Engineer		X	
Dalle, J. R.	NSNF/QA Specialist		X	X
Davis, R. D.	DOE-ID/NSNF/QA Program Manager	X	X	
Hendrickson, R. W.	NSNF/QA Specialist	X	X	
Kido, Clarke	NSNF/QA Specialist	X	X	X
Loo, H. H.	NSNF/Technical Lead	X	X	
MacKay, N. S.	NSNF/QA Specialist	X	X	X
McCardell, J. L.	NSNF/Sr. Admin. Specialist		X	
McManamon, W. L.	NSNF/Document Control Coordinator		X	
Mena, Arturo	NSNF/QA Specialist			X
Passey, Tana	NSNF HLW Program Support		X	
Truman, D. W.	NSNF/QA Specialist	X	X	X
Wheatly, P. D.	NSNF/Technical Lead	X	X	X

Legend:

NSNF..... National Spent Nuclear Fuel
DOE-ID..... U.S Department of Energy-Idaho
QA.....Quality Assurance

ATTACHMENT 2
SUMMARY TABLE OF AUDIT RESULTS

QA Program Sections	Implementing Documents	Details (✓) List	Deficiency Reports	CDAs	Recommendations	Program Adequacy	Procedure Compliance	Overall
1	PMP 1.01, Rev. 2, DAR 2-1	Pages 1-4	N	N	N	SAT	SAT	SAT
2	PMP 2.01, Rev. 2, ICN 1	Pages 5-6	N	N	N	SAT	SAT	SAT
	PMP 2.04, Rev. 4	Pages 7-10	N	N	N	SAT	SAT	
	PMP 2.05, Rev. 3, DR 263	Pages 11-13	N	N	N	SAT	SAT	
3	PMP 3.01, Rev. 1	Pages 14-17	N	N	N	SAT	SAT	SAT
4/7	PMP 4.01, Rev. 2, ICN1, DAR 322, 336	Pages 18-23	N	N	N	SAT	SAT	SAT
5	PMP 5.01, Rev. 3, ICN 2	Pages 23-28	N	N	N	SAT	SAT	SAT
	PMP 5.02, Rev. 6	Pages 29-32	DIR-9	N	N	SAT	UNSAT	
6	PMP 6.01, Rev. 5, ICN 1	Pages 33-38	N	N	N	SAT	SAT	SAT
	PMP 6.02, Rev. 2	Pages 39-42	N	N	N	SAT	SAT	
11	PMP 11.01, Rev. 2, DAR 170, 231, & 269	Pages 43-44	N	N	N	SAT	SAT	SAT
16	PMP 16.02, Rev. 5, ICN 1	Pages 45-46	EM-01-D-145	N	N	SAT	UNSAT	SAT
	PMP 16.03, Rev. 1	Pages 47-48	N	N	N	SAT	SAT	
17	PMP 17.01, Rev. 3, DAR 315	Pages 49-55	N	N	#2 CIRS 2068	SAT	SAT	SAT
18	PMP 18.01, Rev. 3,	Pages 56-58	EM-01-D-144	N	N	SAT	UNSAT	SAT
	PMP 18.02, Rev. 5	Pages 59-62	N	N	N	SAT	SAT	
	PMP 18.03, Rev. 4, ICN 1	Pages 63-66	N	N	N	SAT	SAT	
	PMP 18.04, Rev. 3	Pages 59-62	N	N	N	SAT	SAT	
SI	PMP 19.01, Rev. 0 DAR 243-244 and 259	Pages 67-69	N	CDA	N	SAT	SAT	SAT

QA Program Sections	Implementing Documents	Details (✓) List	Deficiency Reports	CDAs	Recommendations	Program Adequacy	Procedure Compliance	Overall
SIII	Scientific Investigation	Pages 43-44	N	N	N	SAT	N/I	SAT
SV	Control of Electronic Management of Data	Page 70	N	N	#1 CIRS 2067	N/A	N/A	N/A
TOTAL		70	3	1	2			

Adequacy.....	Procedures Contain Requirements
CDA.....	Corrected During Audit
Compliance.....	Procedures Implemented
N/A.....	Not Applicable
N.....	None
N/I.....	No Implementation
Overall.....	Summary of Sections
PMP.....	Program Management Procedures
SAT.....	Satisfies Criteria